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Patents Form 1/77

Act 1977
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22 APR 1999
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P01/7700 0.00 - 9909301.5

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
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1. Your reference DCW/VSW

2. Patent application number *(The Patent Office will fill in this part)* 22 APR 1999 **9909301.5**

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

KCI MEDICAL LIMITED
Two Rivers
Station Lane
Witney
Oxfordshire OX8 6BH

Patents ADP number *(if you know it)* 06896280001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

"Wound treatment apparatus employing reduced pressure"

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Brookes & Martin

High Holborn House
52/54 High Holborn
London WC1V 6SE

Patents ADP number *(if you know it)* 471001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

yes

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	6
Claim(s)	1
Abstract	
Drawing(s)	3 + 3

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Brookes & Martin Date 22 April 1999

BROOKES & MARTIN

12. Name and daytime telephone number of person to contact in the United Kingdom

0171 242 9631 - David C. Woodcraft

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Notes

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d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

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WOUND TREATMENT APPARATUS EMPLOYING REDUCED PRESSURE

The present invention relates to an apparatus for the healing of wounds and more particularly to preventing progression of partial-thickness burns.

Where a person suffers a burn, the dermal and epidermal layers in the region of the wound are damaged. Closure of the resulting wound is important to prevent loss of body fluids and invasion by micro-organisms. In the case of a partial-thickness burn, epithelial and subcutaneous tissue adjacent to the wound will migrate outwards and eventually grow new tissue over the wound. A wide array of wound coverings have been developed to expedite wound closure and allow the natural processes of repairing the damaged tissue to proceed.

The prognosis of a wound caused by a burn depends on the severity of the injury and particularly the depth of the burn. In general, a partial-thickness burn will heal more quickly and with less complications than a deeply penetrating burn. It has been observed that partial-thickness burns often deteriorate and become more serious, deeper burns, if not treated promptly after incurring the burn injury.

The hands more often suffer burn injuries than other parts of the body. Probably, this is due to the natural reaction of attempting to protect the face with the hands and, in many cases, the burn injury is to the backs of the hands. Other parts of the body which more frequently suffer burns may be the arms, feet and legs.

The present invention seeks to provide apparatus for treating injuries to a part of the body, especially injuries caused by burns.

According to one aspect of the invention there is provided apparatus for stimulating healing of wounds which comprises an envelope for receiving an affected part of the body, said envelope including a substantially air-tight cover and a porous pad within the cover, said cover being adapted to contact the wound surface, and connection means for connecting the interior of the envelope to a source of negative pressure.

By substantially "air-tight" cover is meant one which is sufficiently air-tight that by applying suction to the porous pad, a pressure below ambient can be maintained within the envelope. It is not, however, necessary for the material of the envelope to be totally air occlusive.

It has been found that when negative pressure therapy using the apparatus of the invention is applied to a burn within a relatively short time of incurring the injury (e.g. within about 12 hours), not only is the rate of healing improved but progression of a partial-thickness burn to a deeper injury is arrested.

In one embodiment, the apparatus of the invention the envelope comprises a glove, sleeve or sock. For example, the apparatus may include a glove formed from a flexible plastics or rubber foam which is contained within a cover of low air-porosity. Typically, the flexible plastics foam is a polyurethane or polyvinyl alcohol foam having intercommunicating cells or a combination of such foams.

Additional features of the present application will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is an exploded perspective view of the porous pad;

Figure 2 is a perspective view when the porous pad is assembled together;

Figure 3 is a perspective view of the porous pad within its cover; and

Figures 4a to 4d show various views of a connector for pneumatically connecting the porous pad to a source of negative pressure.

The embodiment shown in the accompanying drawings is designed for use in treating burns to the hand.

It will be appreciated that various appropriate modifications are possible for treating burns to other parts of the body, such as feet within the scope of the invention.

Figures 1, 2 and 3 show a hand wound apparatus (10) comprising a porous pad having a lower base (22), a middle section (24) and an upper section (26) incorporated within a cover (12) of low air porosity. The porous pad is in the form of a glove and may be constructed by fixing the upper section (26) to the base (22) while retaining the middle section (24) within the cavity so formed. Typically, the porous pad is a reticulated plastics foam, and may be formed by gluing or welding the separate sections together. When placed inside the pad, the hand is held in place with fingers spread by finger- locators (25) and V-cut type grooves (14). As shown in Figures 2 and 3, the foam may be shaped to provide for a separate supporting compartment for the thumb to aid the attainment of the optimum positions of the fingers and thumb for healing. The pad is preferably made from a reticulated foam such as polyurethane as described in PCT application WO 96/05873, polyvinylacetate, or polyvinylalcohol foam or a combination thereof.

Referring to Figure 3, the assembled pad is then inserted within cover (12). Cover (12) is an e..velope formed from air-impermeable sheet material and is sized to encompass the glove-shaped porous pad. One end of the cover (12) has a large opening which is closable by an easily re-sealable means (4) such as a zip-type seal used on food bags. The other end (8) includes a substantially impermeable pressure-sensitive acrylic resin adhesive (9), ,the underside of which is secured as a tight seal to the patient's skin. The open end (8) is open and is tapered as shown. Open end (8) may carry a pressure-sensitive adhesive (9) on its inner surface for sealing attachment to the wrist or lower arm of the patient. By providing a taper, the open end can be cut to a size such that the opening will fit snugly around the patient's wrist. Attached to the cover (12) in the region of a central part of the porous pad is a connector (100).

Figures 4a to 4d show various views of the connector (100) and it will be seen that it comprises a moulded plastics disk-like cup (101) and suction port having a centrally positioned spout (102) and aperture (106). The connector (100) is firmly attached to the cover by an adhesive. The spout (102) is sized to accept as a closely sliding fit, the end of a single or multi-lumen tube (30) which emerges from beneath the wound cover (12). Tube (30) may be constructed as described in co-pending patent application WO 97/18007. Where a multi-lumen tube is used, one lumen can be used for measuring the pressure at the burn site. It is also within the scope of this invention to irrigate the burn or other wound through one of the lumens or via a separate connector to the foam pad. The connector or connectors can be used to introduce drugs, e.g. antibiotics, to the wound site. The cover drape (12) is preferably

made from a flexible film of low air permeability such as polyurethane and may include a protective layer of polyethylene. Suitable materials are described in GB patent application No. 9819678.5.

In use, the hand of a patient having a burn injury is introduced into the outer cover (12) via the open end (8). Re-sealable opening (4) may then be opened and folded back to expose the injured hand. The hand is then introduced into the porous pad which may be pre-assembled or assembled in situ around the injured hand. In the latter case, it may be convenient to fix the upper section (26) to the lower section (24) by suturing or stapling, rather than gluing or welding the foam. With the foam pad in place encompassing the injured hand, the cover (12) is drawn back over the porous pad and the opening (4) re-sealed. Spout (102) is then connected by a tube to a suction pump, e.g. using the technique described in WO 97/18007. Pulsed, intermittent or continuous negative pressure may be applied to the patient's hand in accordance with a programme which may be controlled automatically by a control device associated with the pump as described in our above patent application. Negative pressure therapy using the apparatus of the invention has been found to stimulate healing of burns and to reduce the progression of cell death beneath a burn injury. Also, by improving blood flow to the wound area, infection is controlled and granulation of the wound is stimulated.

One additional beneficial effect of therapy using the apparatus of this invention is that during therapy, the hand is held firmly in a half-closed position, which is the optimum position for promotion of healing. This can be further encouraged by the

introduction of a rigid or semi-rigid splint, e.g. of plastics, which is formed or moulded into the desired shape, the collapsed dressing being strapped to the splint during or after application of the suction, so that the desired healing position can be maintained after release of the suction.

The suction pump is preferably controlled by control means including a pressure transducer for monitoring pressure at the wound site as described in our above PCT application. A timer device may also be associated with the pump to provide on/off operation if necessary at selected intervals. The apparatus may also include a canister located between the porous pad and the pump to collect wound exudate. Typically, the pump is a diaphragm pump but other types of pumps and equivalent components, such vacuum bottles, may be substituted. The apparatus may also be used with a wall suction source as described in GB patent application No. 9822341.5.

The terms and expressions which have been employed are used as terms of description and not of limitation. Although the present invention relates mainly to partial-thickness burns, it is understood that the present invention maybe used with open wounds as well as a possible treatment of pressure sores.

CLAIMS:-

1. Apparatus for stimulating healing of wounds which comprises an envelope for receiving an affected part of the body, said envelope including a substantially air-tight cover and a porous pad within the cover, said pad being adapted to contact the wound surface, and connection means for connecting the interior of the envelope to a source of negative pressure.

2. Apparatus as claimed in claim 1 wherein the envelope comprises a glove, sock or sleeve.

3. Apparatus as claimed in claim 2 which is intended for treating wounds to the hand and comprises a glove formed from a flexible plastics or rubber foam and an external cover of air-impermeable sheet material.

4. Apparatus as claimed in claim 3 wherein the connection means comprises a tube which communicates with the foam within the cover.

5. Apparatus as claimed in any one of the preceding claims wherein the cover has a re-sealable opening which permits the wound to be inspected at intervals.

6. Apparatus as claimed in any one of the preceding claims wherein the source of negative pressure is a suction pump.

7. Apparatus as claimed in any one of the preceding claims which includes a canister for collecting wound exudate.

Fig. 1

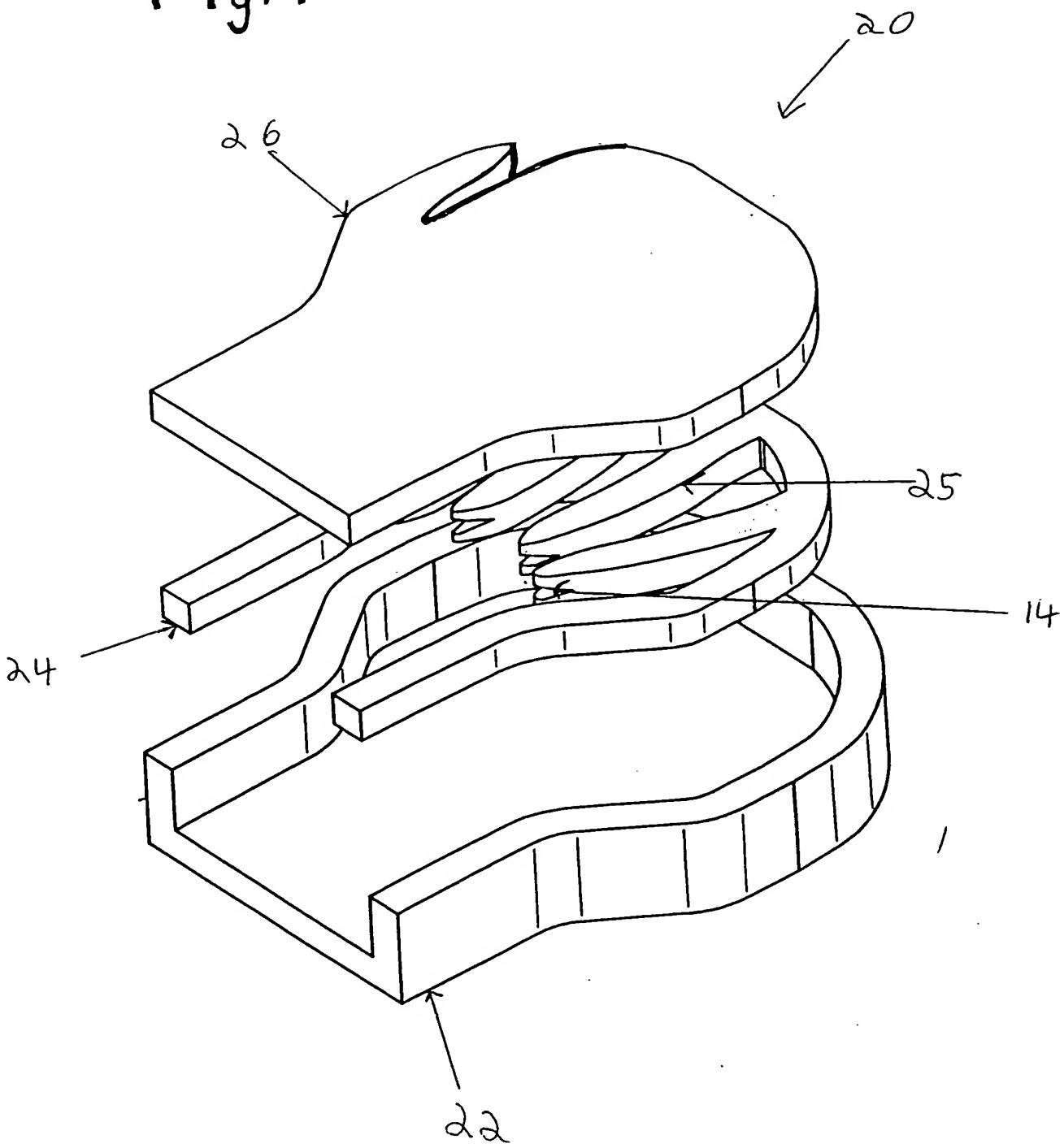


Fig. 2

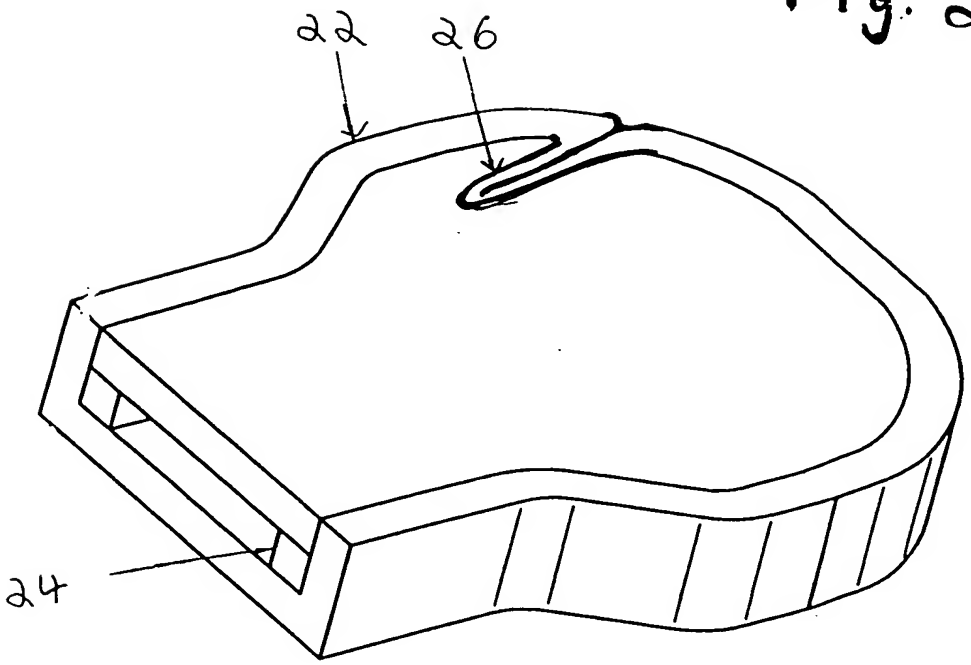
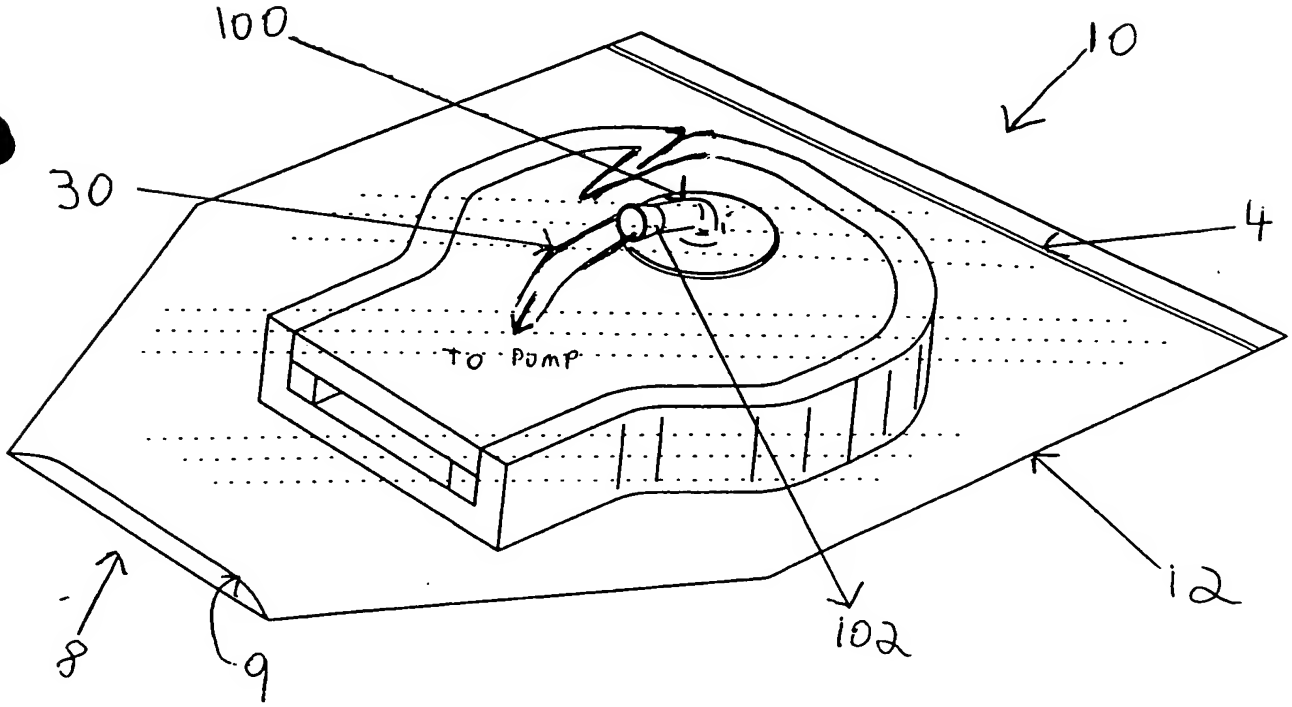


Fig. 3



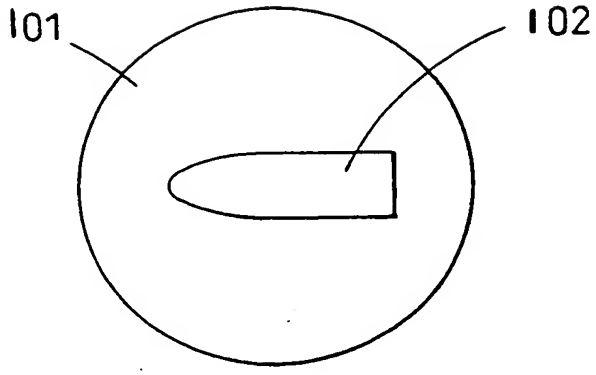


Fig. 4A

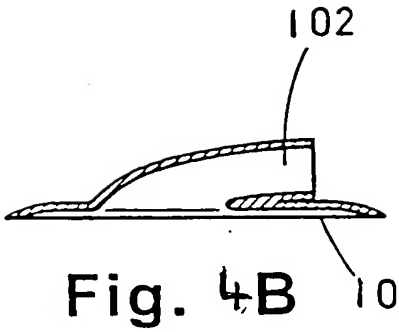


Fig. 4B

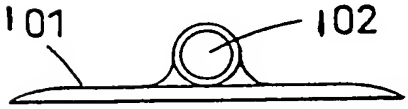


Fig. 4C

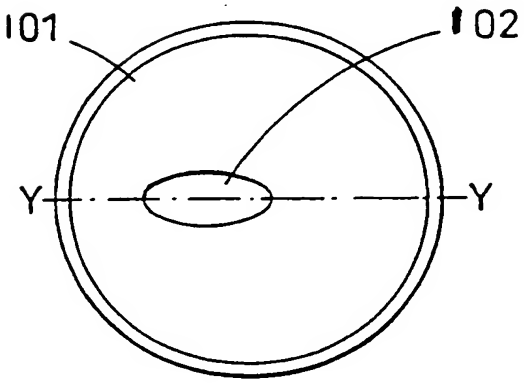


Fig. 4D